

***Remarks***

Upon entry of the foregoing amendment, claims 150-170 are pending in the application, with claims 150, 160, and 170 being the independent claims. Claim 160 has been amended to correct a minor grammatical error. This change introduces no new matter, and its entry is respectfully requested.

Based on the above amendment and the following remarks, applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Initial Matters***

The present Office Action is marked as a final Office Action. Pursuant to MPEP § 706.07(a), "second or subsequent actions on the merits shall be final, **except** where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. § 1.97(c)...." (emphasis added). Further, "[a] second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed." *Id.* (citing MPEP § 904).

In the present application, only minor claim amendments were made in applicants' Amendment and Reply in response to the previous Office Action, and those amendments were merely clarifications of the claim language. In the previous Amendment and Reply, applicants' traversed the presented prior art rejections, which

were based on U.S. Patent No. 5,957,949 (Leonhardt *et al.*), because the '949 patent failed to disclose a valve support having an axial length sufficient to extend from a position of a native annulus, past the replacement valve, the commissure points, and the patient's coronary ostia, and into an ascending aorta, as recited in claim 150, and also failed to disclose similar recitations in claims 160 and 170.

In the present Office Action, the Examiner agrees that the '949 patent is "silent with respect to the length of the valve support," (Office Action, p. 4), and introduces a new ground of rejection based on the '949 patent in view of U.S. Patent No. 6,305,436 (Andersen *et al.*). Because this new ground of rejection was not necessitated by applicants' claim amendments, and is not based on an information disclosure statement filed during the period set forth in 37 C.F.R. § 1.97(c), applicants respectfully submit that the current Office Action is incorrectly marked as a final Office Action. Applicants therefore request that the finality of the pending Office Action be withdrawn, and that the present Amendment and Reply should be considered under 37 C.F.R. § 1.111.

***Rejections under 35 U.S.C. § 103***

Claims 150-153, 155-163, and 165-170 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,957,949 (Leonhardt *et al.*) in view of U.S. Patent No. 6,305,436 (Andersen *et al.*). Claims 154 and 164 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,957,949 (Leonhardt *et al.*) in view of U.S. Patent No. 5,104,404 (Wolff).

The Office Action states that the '949 patent discloses: a valve support having an axial length sufficient to extend from a position of a native annulus, past the replacement valve, the commissure points, and the patient's coronary ostia, and into an ascending

aorta, as recited in claim 150; a valve support configured to extend, when implanted into a patient, from a native annulus at the proximal portion to an ascending aorta at the distal portion, past a location of the patient's coronary ostia, as recited in claim 160; or a valve support sized and shaped to extend from a position of the native annulus, past the replacement valve, the commissure points, and the patient's coronary ostia, and into an ascending aorta when the valve support is implanted in a patient and the replacement valve is positioned in a native aortic valve annulus, as recited in claim 170. Office Action, pp. 2-4. However, on the next page of the Office Action, the Examiner states that the '949 patent is "silent with respect to the length of the valve support," apparently recognizing that the '949 patent provides no disclosure of a valve support having sufficient length to extend from a native annulus, past the coronary ostia, and into an ascending aorta. Office Action, p. 4. The Office Action then states that the '436 patent "teaches a stent supporting a prosthetic valve, where the stent's length may be varied."

Applicants respectfully disagree that the features recited in claims 150, 160, or 170 are disclosed or suggested by the '949 patent or the '436 patent, taken alone or in combination, and submit that the Office Action fails to establish a *prima facie* case of obviousness as to claims 150, 160, and 170.

The '949 patent discloses a valve stent 20 that implanted at the location of the mitral valve, the aortic valve, or in the aorta. '949 patent, col. 5, ll. 41-42; col. 9, l. 63 - col. 10, l. 30; Figs. 2, 3, and 9D. The stent 20 is configured to conform to the tissue immediately around the location of the mitral valve and/or aortic valve, or to bond to the aorta. '949 patent, col. 5, ll. 48-52; col. 9, l. 63 - col. 10, l. 30. The '949 patent does not teach a prosthetic cardiac valve assembly configured to extend past the coronary ostia

and into the ascending aorta. As would be recognized by one skilled in the art, the valve replacement stent disclosed in the '949 patent would not be of sufficient length to implant in the aortic valve annulus and also extend into the ascending aorta, as there is no such disclosure in the '949 patent, and the only figures of the '949 patent showing the artificial valve implanted in an annulus, FIGS. 2 and 9D, show that the valve is configured to conform to the tissue around an annulus.

The '436 patent discloses a stent for providing reinforcement to the lumen of a peristaltic organ. '436 patent, col. 1, ll. 61-62. Specifically, the '436 patent contemplates the use of such a stent in an esophagus. '436 patent, col. 6, ll. 50-53; fig. 2 - fig. 3e. The '436 patent further teaches that when used as such a valve, "the small diameter end [is] oriented downstream." '436 patent, col. 16, ll. 1. This feature is inconsistent with the present invention wherein the larger diameter end of the valve support extends downstream ("past the coronary ostia and into the ascending aorta"). Clm. 150.

The Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *In re Piasecki*, 745 F.2d 1468, 1471-73, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984). "Rejections on obviousness cannot be sustained by merely conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006).

Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006); *see also* MPEP

2143.01. However, to reject a claim based on this rationale, the Examiner must articulate a finding that there was some teaching, suggestion, or motivation to combine or modify the teachings of the prior art, and a finding that there was a reasonable expectation of success. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. *See* "Examination Guidelines for Determining Obviousness under 35 U.S.C. § 103 in view of the Supreme Court decision in KSR International v. Teleflex Inc.", *Fed. Reg.* 72:57526-57535, 57534 (October 10, 2007), hereinafter "Examination Guidelines." To this end, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The Office Action asserts that it would have been obvious to use the teachings of the '436 patent to extend the valve support into the ascending aorta. However, a person of skill in the art would have had no motivation to modify the teachings of the '949 patent, which discloses a stent for replacement of a mitral or aortic valve, col. 5, ll. 41-42, with the stent structure from the '436 patent that does not include leaflets and is directed towards stents for use in peristaltic organs; the function of which are fundamentally different from that of the heart.

Furthermore, altering the stent of the '949 patent in view of the '362 patent would render the stent of the '949 patent unsuitable for its intended purpose. As noted above, the '436 patent teaches that when used as a valve, "the small diameter end [of the '436 stent is] oriented downstream." '436 patent, col. 16, ll. 1. The stent 20 of the '949 patent

is configured to conform to the tissue immediately around the location of a native valve annulus in order to sealingly engage the tissue of the native valve annulus. Extending stent 20 of the '949 patent based on the disclosure of the '436 patent would result in a stent that does not conform to the tissue immediately around the native valve annulus, and thus would result in a stent that is not securely anchored in the native annulus. A prosthetic heart valve must be securely anchored to remain in position during operation. Thus, if the teachings of the '949 patent were modified to include an elongated stent as disclosed by the '436 patent, one of skill in the art would not have a reasonable expectation of success in securely implanting the modified device in a native aortic valve annulus.

Thus, neither the '949 patent nor the '362 patent, taken alone or in combination, render obvious each and every limitation of claims 150, 160, and 170. Claims 151-159 depend from and add limitations to claim 150, and are therefore patentable for at least the same reasons as claim 150. Claims 161-169 depend from and add limitations to claim 160, and are therefore patentable for at least the same reasons as claim 160.

Applicants therefore respectfully request that the rejections of claims 150-170 be reconsidered and withdrawn, and that claims 150-170 be allowed.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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